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This *Planning Guide* is intended to serve as a planning resource for Health and Medical Delivery Organizations (HMDOs). Nothing in the *Planning Guide* shall be considered to be a public health directive by the Virginia Department of Health or legal advice by Troutman Sanders LLP. The components of the *Planning Guide* are intended to be tools to assist HMDOs in developing their critical resource shortage response plans. Each HMDO's response plan should be tailored to meet its specific needs and should be created after thorough evaluation of the challenges different types of disasters may create for the organization. Like any printed resources, these materials may not be complete, may become out of date over time and/or may need to be revised or updated. References to sites on the Internet are provided as a service for users of the *Critical Resource Shortages Planning Guide Implementation Toolkit (Implementation Toolkit)* and do not constitute or imply endorsement of these materials by Troutman Sanders or the Virginia Department of Health. Neither Troutman Sanders nor the Virginia Department of Health are responsible for the content of pages found at these sites. URL addresses listed in the *Implementation Toolkit* were current as of the date of publication.

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Over the last four years, a few organizations have come to the forefront to take the lead in critical resource shortage response planning and the development of this *Critical Resource Shortages Planning Guide* (*Planning Guide*). The Virginia Department of Health (VDH) and the Virginia Hospital and Healthcare Association (VHHA) were among the first to recognize healthcare providers' concerns about the use of "altered" standards of care in a disaster and the need for more definitive guidance in this area. Through a collaborative partnership with Troutman Sanders LLP (Troutman Sanders), VDH, VHHA and Troutman Sanders were able to convene a multi-disciplinary workgroup, which created the first version of the *Planning Guide*. VDH, VHHA and Troutman Sanders continued to work together, reconvening the workgroup periodically to update the *Planning Guide* as more literature in this area became available.

The Georgia Division of Public Health (GA DPH) along with the Georgia Association of Emergency Medical Services (GAEMS) recognized a need in their state for more definitive guidance on "altered" standards of care. Building upon the work done in Virginia, Troutman Sanders was able to work with GA DPH, GAEMS and Georgia healthcare providers to expand the reach of the *Planning Guide* by incorporating coordination between all healthcare providers and recognition that planning may not occur at the single provider level. GA DPH's and GAEMS' commitment to the *Planning Guide* and the process contained therein is evidenced by the fact that they have commissioned the development of an *EMS Implementation Guide*, which will be available later this year.

Most recently, Sentara Norfolk General Hospital (Norfolk General) has devoted a tremendous amount of time and resources to implementing the process outlined in the *Planning Guide* at its facility. The dedication of the many physicians, nurses, support staff, ethicists, chaplains, and administration representatives resulted in the successful development of a draft Critical Resource Shortage Response Plan. The lessons learned during this pilot implementation have served to enhance the *Planning Guide* and the *Hospital Implementation Guide* and will make them much more effective tools for others to use in the near future.

It is our hope that other public health officials, emergency managers, emergency planners, healthcare executives, and others involved in preparing Health and Medical Delivery Organizations to respond to critical resource shortage events will find this *Planning Guide* useful in their efforts to enhance their level of preparedness for such events.

REVIEWERS

The Critical Resource Shortages Planning Guide and the Hospital Implementation Guide were reviewed in draft form by individuals who were involved in the creation of prior versions of the Planning Guide, those who were involved in working through the process suggested by the Planning Guide at Sentara Norfolk General Hospital, and experts in emergency and disaster planning. We would like to thank the following individuals for their thoughtful and thorough review of the Planning Guide and Hospital Implementation Guide and their insightful feedback:

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Tiffany R. Shifflett, a member of the Troutman Sanders Healthcare Practice Group, served as the project coordinator for the Centers for Disease Control and Prevention Essential Services Grant, which funded the pilot implementation of the process described in the *Planning Guide* at Sentara Norfolk General Hospital.

Other members of the Troutman Sanders team helped to prepare the *Implementation Toolkit*, including Paige Fitzgerald, Craig Elkins, Nancy Kaplan and Frank McGraw.

TABLE OF CONTENTS

INTRODUCTION	I
OVERVIEW OF T	THE PLANNING GUIDE
HISTORY OF TH	E PLANNING GUIDE
DEFINITIONS	
GLOSSARY OF A	ACRONYMS14
PLANNING GUII	DANCE
Chapter 1.	Develop the critical resource shortage response planning infrastructure
Chapter 2.	Conduct a Critical Resource Vulnerability Analysis
Chapter 3.	Develop an ethical framework that will guide the development of the Critical Resource Shortage Response Plan and associated Protocols
Chapter 4.	Develop an operational infrastructure that will support an effective response to a critical resource shortage event
Chapter 5.	Identify or develop resource-specific Protocols21
Chapter 6.	Create an infrastructure to support the development, implementation and operationalization of Ad Hoc Protocols during a critical resource shortage event
Chapter 7.	Engage in collaborative planning and coordination with other Health and Medical Delivery Organizations
Chapter 8.	Determine how the Critical Resource Shortage Response Plan will be evaluated and maintained
Chapter 9.	Obtain approval of the Critical Resource Shortage Response Plan and integrate it into all relevant emergency operations plans
Chapter 10.	Develop comprehensive communication plans with strategies addressing communications to key audiences

INTRODUCTION

Health and Medical Delivery Organizations (HMDOs) are on the front lines of an effective response to any disaster, including a public health emergency. Continuation of effective medical care is a basic component of a community's ability to respond to and recover from a disaster. There is now widespread acceptance of the fact that assuring the ability of HMDOs to effectively treat the victims of a disaster while also continuing their provision of basic medical services is absolutely essential to an effective emergency response. Hurricane Katrina will forever remind us of what happens to disaster victims, and the community-at-large, when the healthcare delivery system breaks down in the wake of a disaster.

It has become abundantly clear that the nation's response to a public health emergency, or other disaster, requires and assumes that HMDOs will continue to be operational and capable of treating both the victims of the disaster and the rest of the community. In other words, HMDOs have an affirmative duty to prepare for disasters and emergencies. On May 5, 2009, Department of Homeland Security Secretary Napolitano said about the 2009 H1N1 pandemic: "We are not in a place where we can simply sit back and see what happens. We have to lean forward. And we have to remain prepared because nature has a way of being a little unpredictable and throwing a curve ball from time to time." This builds on a comment made by Dr. Richard Besser, Director of the CDC Coordinating Office for Terrorism Preparedness and Emergency Response, on May 4, 2009 about health system preparedness for the H1N1 outbreak: "[T]here are things that institutions can do to be ready and decrease the impact on their facilities and their communities." These statements are simply the latest in a long line of clearly articulated expectations for HMDOs to be prepared to respond to disasters and emergencies.

Being prepared, however, is not enough. HMDOs must also be able to effectively respond during disasters and emergencies. This requires not only being able to implement the plans that they have created, but also to modify their plans in response to the changing conditions presented by the disaster. While this may be basic, it is most assuredly not simple. The delivery of medical care today is extremely complex and relies upon an intricate and elaborate interplay of highly trained personnel, complex technology, and the availability of specialized resources. For both diagnosis and treatment, technology has enabled the provision of medical services that were literally unimaginable 40 years ago, let alone during the last great pandemic in 1918. Our healthcare delivery model has evolved to incorporate these wonderful tools into the very fabric of the care model and the way that physicians and other healthcare and medical personnel are educated and trained.

While no one can question the tremendous value of these advances, they do present some unique challenges for HMDOs in terms of their ability to effectively prepare for and respond to disasters and emergencies. These advances have created expectations among patients that

² Besser, Richard. "CDC Briefing on Public Health Investigation of Human Cases of H1N1 Flu (Swine Flu)." 4 May 2009. (Transcript available online at http://www.cdc.gov/media/transcripts/2009/t090504.htm (last visited September 28, 2009).)



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¹ Napolitano, Janet. "Media Briefing on the H1N1 Flu Outbreak." U.S. Department of Health and Human Services. Washington D.C. 5 May 2009. (Transcript available online at http://www.dhs.gov/ynews/releases/pr 1241615110532.shtm (last visited September 28, 2009).)

HMDOs will use every resource available to save lives, unless directed not to by the patient. The implicit assumption behind this expectation is that every resource will always be available to treat a patient in need. During a critical resource shortage event (CRSE)³, this simply will not be true. Resources will be scarce so HMDOs will be forced to modify the way they provide care to "stretch" these scarce resources, or, in more extreme situations, allocate the resource.

These changes in care, sometimes referred to as "altered standards of care," have become the target for all manner of criticism and, in some cases, hysteria around the possible abandonment and neglect of patients under the rubric of responding to a disaster. Unfortunately, the tragic events that unfolded at Memorial Medical Center in New Orleans in the days following the landfall of Hurricane Katrina served only to exacerbate both the concern and hysteria around "altered standards of care." While those events, and the deaths of patients, will continue to be debated, we cannot allow the debate around HMDO preparedness and response to be consumed by that tragic event. The fact of the matter is that the way in which medical care is provided is going to change in a disaster or public health emergency.

This change will be driven by the shortage of critical resources. To continue providing care as it is provided today, HMDOs must have all of the resources that they have today. Whether that resource is personnel, equipment, supplies, or space, a shortage of that resource (and probably multiple resources in combination) on a large scale across a region, state or nation will drive the need to alter the standard of care. No one wants to alter the standard of care. The necessity of altering the standards is simply a function of the fact that the resources needed to provide that care will no longer be available. These resource shortages will occur whether HMDOs plans for them or not. The only choice is whether HMDOs leave themselves at the mercy of these events or whether they plan proactively for how to deal with the shortages when they do occur.

The key to responding effectively to a disaster or public health emergency is to plan. Likewise, the key to responding effectively to a CRSE caused by an emergency or disaster is to plan. This *Critical Resource Shortages Planning Guide* (*Planning Guide*) will enable HMDOs to proactively plan for the inevitable shortages of critical resources that will occur in the wake of a disaster. This planning will give HMDOs the best chance of maintaining health and medical care services during and after the disaster.

The *Planning Guide* was designed as a tool that provides a systematic approach to addressing the complex issues surrounding modification of care and, in some cases, even allocation of resources, during large scale disasters and emergencies that result in CRSEs. (Refer to the History of the *Planning Guide* below for more background information.) The approach described in the *Planning Guide* is flexible enough to be used by any HMDO or group of HMDOs (Planning Unit). HMDOs that follow the process outlined in the *Planning Guide* will create a Critical Resource Shortage Response Plan (CRSRP) containing, among other things, ethical and operational frameworks for responding to CRSEs, and resource-specific Protocols that providers at the point of care can use to modify care provided by or with, or to allocate,

³ A CRSE is a circumstance in which a critical resource is depleted, and all alternate methods of obtaining the critical resource have been exhausted, such that remaining resources will not allow an HMDO to treat patients in accordance with the traditional standard of care.



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specific critical resources. (Refer to the Overview of the *Planning Guide* below for more information.)

The *Planning Guide* is an excellent tool, however, like any tool it has to be used appropriately to be effective. Most HMDOs do not have the infrastructure or the management resources to easily implement the *Planning Guide* without some assistance. In response to this need, we have developed the *Critical Resource Shortages Planning Guide Implementation Toolkit* (*Implementation Toolkit*) to help those who are involved in preparing HMDOs for CRSEs. This *Implementation Toolkit* contains helpful resources including a *Hospital Implementation Guide*, which serves as an "instruction manual" or "teacher's edition" of the *Planning Guide*; template Power Point presentations with speaker's notes to accompany select chapters of the *Hospital Implementation Guide*; and, other practical, hands-on tools that will enable the effective implementation of each section of the *Planning Guide*.

Looking at emergency preparedness for HMDOs through the critical resource shortage response planning lens is extremely daunting. Indeed, many become discouraged at the enormity and complexity of the task and simply give up saying that they will "do the best they can" when the disaster arises. Unfortunately, this approach could expose the HMDO to significant liability for failing to meet its duty to effectively plan for and respond to CRSEs. Certainly, the plans will not be executed perfectly and, even if executed effectively, they will not always lead to the intended results. However, not having plans or not being able to effectively implement those plans is a recipe for a disaster on top of the disaster, and could result in significant liability for HMDOs. The *Planning Guide* and *Implementation Toolkit* are intended to provide HMDOs with the planning resources that they need to avoid such a tragedy.

OVERVIEW OF THE PLANNING GUIDE

The Critical Resource Shortages Planning Guide (Planning Guide) is a step-by-step framework for helping Health and Medical Delivery Organizations (HMDOs) plan for the inevitable shortage of critical resources that will occur during a disaster or public health emergency. The Planning Guide is divided into 10 chapters, each of which helps the planner identify key issues and follow a logical, step-by-step process to address those issues.

The *Planning Guide* process begins by creating the infrastructure within which the remainder of the *Planning Guide* process will occur. This includes identifying a Convener, an Implementation Team and Planning Units. The Planning Unit is the level at which planning occurs. It can be a single HMDO, a group of HMDOs, a community, a region, or a state depending on the relationship, characteristics and needs of the HMDOs within that Planning Unit. The Planning Unit may remain constant for all activities in the *Planning Guide* or it may vary based on the task. For instance, a group of HMDOs in a region may decide to develop a consistent ethical framework that will guide the development of Protocols throughout the region. However, each HMDO may develop its own operational infrastructure since they each operate differently.

Upon completion of the process described in the *Planning Guide*, a Planning Unit will have a complete Critical Resource Shortage Response Plan (CRSRP) which will include the following elements:

- an ethical framework for planning and decision-making during a critical resource shortage event (CRSE);
- an operational infrastructure for implementing the CRSRP;
- Protocols for specific critical resources;
- an infrastructure for developing Ad Hoc Protocols during a CRSE; and
- a process for coordinating critical resource shortage response planning efforts with other HMDOs.

The **ethical framework** will allow the Planning Unit to make these very complicated critical resource shortage response decisions in a way that will be recognized by all participants as having a solid ethical foundation. The *Planning Guide* walks the Planning Unit through a three step process to develop this ethical framework by (i) identifying ethical principles, (ii) defining the Goal of the CRSRP and Protocols, and (iii) determining conceptually how to allocate scarce resources to meet its Goal.

An effective response to a CRSE will also require that each Planning Unit have an **operational infrastructure** that supports and aids the implementation of the CRSRP and associated Protocols. While the majority of HMDOs have an emergency response infrastructure, many Planning Units have not yet developed the type of infrastructure that will be needed to efficiently implement a CRSRP and the associated Protocols. The *Planning Guide* provides a process for the development of this infrastructure that will support the consistent development, implementation and operationalization of the CRSRP and associated Protocols.



A CRSRP will include numerous **Protocols** which describe how the Planning Unit will "alter" the standard of care for specific critical resources to respond to a shortage of that resource during a disaster. Protocols include both a description of how care provided by or with the critical resource will be modified to "stretch" the resource and how the resource will be allocated after modifications have been made but demand still exceeds supply. Federal, state and/or local Protocols (Governmental Protocols) may already exist for some critical resources. In those cases, the Planning Unit is encouraged to review these Governmental Protocols to determine how they can be implemented by its members. For those critical resources for which no Governmental Protocols exist, the Planning Unit will have to develop its own Protocol. The *Planning Guide* provides a process for both identifying and evaluating existing Governmental Protocols and for drafting original Protocols.

Given the vast number of critical resources used in healthcare today, the Planning Unit will not be able to develop Protocols to address the scarcity of all critical resources identified in and prioritized by their Critical Resource Vulnerability Analysis. Moreover, the Planning Unit cannot anticipate all of the potential critical resources that may become scarce during a disaster or emergency. These unplanned or unforeseen CRSEs will cause the Planning Unit to have to develop Protocols to address the scarcity in the midst of an event. These Protocols developed in the midst of an event are called **Ad Hoc Protocols**. The *Planning Guide* provides a process for creating the infrastructure that will support the development, implementation and operationalization of Ad Hoc Protocols during a CRSE.

HMDOs do not provide care in isolation. Each Planning Unit will need to **coordinate their CRSRP with other HMDOs** to ensure an effective and efficient response to the CRSE. The *Planning Guide* identifies issues that need to be addressed through this coordination and a process for engaging these HMDOs in discussions.

After a CRSRP has been completed, the Planning Unit will need to:

- incorporate the CRSRP and associated Protocols into their Emergency Operations Plan:
- communicate the content of the CRSRP and associated Protocols to all relevant stakeholders;
- provide training on the implementation of the CRSRP and associated Protocols;
 and
- continue to test, review and revise, as needed, the CRSRP and associated Protocols to ensure they are up to date and ready for implementation when a CRSE occurs.

The *Planning Guide* process will assist the Planning Unit with completing these key steps to finalize and maintain their CRSRP.

Recognizing just how complicated this process is, specific implementation tools are also available to facilitate effective implementation of the *Planning Guide*. The *Critical Resource Shortages Planning Guide Implementation Toolkit* (*Implementation Toolkit*) contains helpful resources including a *Hospital Implementation Guide*, which serves as an "instruction manual" or "teacher's edition" of the *Planning Guide*; template Power Point presentations with speaker's



notes to accompany select chapters of the *Hospital Implementation Guide*; and, other practical hands-on tools that will enable the effective implementation of each section of the *Planning Guide*.

We hope that this *Planning Guide* and the *Implementation Toolkit* will be useful tools for HMDOs to use in their pandemic preparedness efforts. Any questions about the Planning Guide or Implementation Toolkit can be directed to Dr. Marissa Levine at (804) 864-7026 or marissa.levine@vdh.virginia.gov, Steve Gravely (804)697-1308 at or steve.gravely@troutmansanders.com or Erin Whaley at (804)697-1389 or erin.whaley@troutmansanders.com.

HISTORY OF THE PLANNING GUIDE

The Initial Creation of the Planning Guide

Healthcare providers are not accustomed to having to modify the use of or allocate inadequate personnel, equipment and supplies on the scale they will confront in a large scale disaster, including a pandemic. The prospects of modification or allocation on this scale understandably cause profound concern within the health and medical care community because such decisions are inextricably tied to liability. Providers understand that they have a duty to render care in accordance with the applicable standard of care or face liability for malpractice. "Altered" standards of care, which by definition do not meet the traditional standard of care, implicate and exacerbate these concerns.

In 2005, providers in Virginia, mainly hospitals and physicians, began expressing concerns about this very issue to the Virginia Hospital and Healthcare Association (VHHA). These concerns were so strong that, at the extreme, some providers were contemplating closing their doors during a pandemic instead of providing care under "altered" standards unless they had some degree of liability protection. VHHA recognized the gravity of the situation and, in coordination with the Virginia Department of Health (VDH), engaged Troutman Sanders LLP (Troutman Sanders) to help it address this issue.

VDH, VHHA and Troutman Sanders (the "Virginia Core Team") recognized that there were substantial misconceptions and confusion among healthcare providers about their realistic liability exposure in relation to "altered" standards. The first step in developing a comprehensive strategy for addressing providers' concerns was for Troutman Sanders to evaluate the current law to determine if any of the liability concerns were legitimate. This evaluation consisted of: (i) an inventory of relevant Virginia laws including the Virginia Emergency Services and Disaster Law, the Virginia Good Samaritan Law, the Virginia State Government Volunteers Act, the statutory "standard of care" in Virginia, and Virginia's Model Jury Instructions for medical malpractice; and (ii) an analysis of applicable laws in relation to a potential "altered" standard of care case, licensure and scope of practice restrictions. Troutman Sanders' evaluation confirmed there was indeed a gap in liability protection in Virginia that left healthcare providers vulnerable to potential claims of malpractice for care provided pursuant to "altered" standards during a disaster.

Beginning in 2006, the Virginia Core Team convened a multi-disciplinary, statewide workgroup to evaluate options to address the liability associated with "altered" standards of care (the "Virginia Altered Standards Workgroup"). The Virginia Core Team selected members for the Virginia Altered Standards Workgroup to assure that diverse perspectives were present without creating a group that was too large to be effective. The Virginia Altered Standards Workgroup was composed of individuals from across the state who represent various healthcare institutions, clinician groups, public health, emergency planning bodies, and state legislature. The Virginia Altered Standards Workgroup sessions were facilitated by Troutman Sanders.



When the Virginia Altered Standards Workgroup first convened, legislative solutions were neither immediate nor guaranteed.⁴ As a result, the Virginia Altered Standards Workgroup pursued a strategy which would allow them to create a tool to help hospitals think and plan for providing care with limited resources. While a few others across the country had devised specific "altered" standards of care algorithms for the allocation of specific resources, like ventilators, the Virginia Altered Standards Workgroup could find no comprehensive planning guide on which to base its work. In the absence of any definitive tools, the Virginia Altered Standards Workgroup undertook an ambitious project of creating such a guide from whole cloth (the *Critical Resource Shortages Planning Guide* (*Planning Guide*)).

The Virginia Altered Standards Workgroup had to come to a consensus on key assumptions regarding the provision of healthcare with scarce resources which will lead to an "altered" standard of care. The two most basic assumptions are as follows:

- 1. When talking about "altered" standards of care, we are really talking about allocation of critical resources in times of shortage. Critical resources are those that are required to sustain human life, prevent permanent disability, or stabilize a person experiencing a medical emergency. These resources will include staff, space and "stuff" such as equipment, medications and supplies.
- 2. While it is commonly recognized within the healthcare industry that "altered" standards of care will have to be employed during a disaster, there is no consistency about the exact nature of those standards. Each disaster situation is unique, as is each healthcare community. This makes it difficult to formulate universal, rigid "altered" standards of care in advance. Instead, it will be most beneficial to offer a *process* that providers can use to identify the content of such standards. That process can then be utilized to develop "altered" standards algorithms as the need arises. This is especially true for a pandemic in which high absenteeism rates will create a shortage of healthcare personnel. In addition, the process can be used to create mechanisms at a healthcare facility to implement an "altered" standard of care if one is promulgated by the state or federal government (e.g., ventilator algorithms).

Recognizing the enormously complex ramifications of these assumptions, the Virginia Altered Standards Workgroup focused its efforts on creating a tool that provides a systematic approach to addressing the complex issues surrounding the allocation and deployment of scarce resources during large scale events, like a pandemic. The result of that effort is the *Planning Guide* which provides a specific, step-by-step framework that Health and Medical Delivery Organizations (HMDOs) across the nation can use to anticipate and respond to critical resource shortage events (CRSEs).

The Evolution of the Planning Guide

Since its first publication in 2006, the *Planning Guide* has been shared with various states and has undergone significant revisions to improve its usefulness as a planning tool. In 2008, the Virginia Altered Standards Workgroup updated the *Planning Guide* by:

⁴ The Virginia Core Team did pursue a legislative solution to address provider's liability concerns. These efforts resulted in the successful passage and enactment of Va. Code § 8.01-225.02 in 2008.



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- including a section devoted to planning to provide palliative care to those who will not receive the critical resource;
- adding a section that encourages hospitals to think about the use of inclusion and exclusion criteria in the development of resource-specific Protocols; and
- adding a section that encourages HMDOs to think about the use of triage officers or committees in implementing Protocols.

In 2008-2009, the Georgia Association of Emergency Medical Services (GAEMS) and the Georgia Division of Public Health (GA DPH) engaged Troutman Sanders (the "Georgia Core Team") to expand the *Planning Guide* to address important planning considerations that were not then a part of the *Planning Guide*. Like the Virginia Core Team, the Georgia Core Team assembled a statewide, multi-disciplinary workgroup to do this work (the "Georgia Workgroup").

The Georgia Workgroup recognized that part of an HMDOs critical resource shortage response planning process should include coordination and collaboration with other HMDOs including, but not limited to, hospitals, EMS providers, long-term care, and home health. An HMDOs ability to effectively and efficiently implement its CRSRP will be based, in part, on these other HMDOs' responses to the event and their ability to continue operations. The Georgia Workgroup added a new section to the Planning Guide to address these interdependent relationships and provide a framework for collaborative planning between various HMDOs.

The Georgia Workgroup also introduced the idea of a "Planning Unit" in the *Planning Guide*. The Planning Unit is the level at which planning occurs. It can be a single HMDO, a group of HMDOs, a community, a region, a state, or the nation depending on the relationship, characteristics and needs of the HMDOs within that Planning Unit. The Planning Unit may remain constant for all activities in the *Planning Guide* or it may vary based on the task.

Given the development over the past few years of various state-level Protocols to address shortages of critical resources (primarily ventilators), the Georgia Workgroup added additional new language to the *Planning Guide* to help facilities and Planning Units identify and evaluate the impact of these Governmental Protocols. Such Governmental Protocols come in a variety of forms such as guidance, standards, allocation algorithms, ethical frameworks, and prioritization schemes. Some of the Governmental Protocols may be mandatory while others remain voluntary. The *Planning Guide* encourages Planning Units to identify any existing Governmental Protocols and establish a mechanism for monitoring the development of these resources.

To the extent that Governmental Protocols are voluntary, a Planning Unit will need to develop its own Protocols for implementation during a CRSE. As noted by the Agency for Health Research and Quality (AHRQ), in the absence of Governmental Protocols, "...it will be incumbent on the [facility] to have a plan or strategy for bringing together the appropriate personnel who can make the best decisions possible" about the use and allocation of scarce critical resources. Regardless of the mandatory or voluntary nature of the Governmental Protocols, HMDOs will need to create an infrastructure for implementing the Protocols. The *Planning Guide* encourages Planning Units and their members to establish the operational

⁵ AHRQ. (Feb 2007). *Providing Mass Medical Care with Scarce Resources: A Community Planning Guide*. Available online at http://origin.www.ahrq.gov/research/mce/mceguide.pdf (last visited September 30, 2009).



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infrastructure that will allow them to implement Protocols, whether they are mandatory Governmental Protocols or developed by the Planning Unit.

While the Georgia Core Team and Workgroup were enhancing the *Planning Guide*, Troutman Sanders was also working with Sentara Norfolk General Hospital (Norfolk General) to implement the *Planning Guide* process. In 2008, the Centers for Disease Control and Prevention (CDC) awarded the Virginia Department of Health (VDH) a competitive grant to conduct a pilot implementation of the *Planning Guide*. Through this grant, Troutman Sanders was given the opportunity to work with Norfolk General to actually engage in critical resource shortage response planning following the process outlined in the *Planning Guide*. This pilot has produced fascinating and important results and lessons learned that have informed further refinement of the *Planning Guide* and the creation of the *Critical Resource Shortages Planning Guide Implementation Toolkit* (*Implementation Toolkit*). The *Implementation Toolkit* contains helpful resources including a *Hospital Implementation Guide*, which serves as an "instruction manual" or "teacher's edition" of the *Planning Guide*; template Power Point presentations with speaker's notes to accompany select chapters of the *Planning Guide*; and, other practical, handson tools that will enable the effective implementation of each section of the *Planning Guide*.

Based on the lessons learned in the pilot project and the creation of the *Hospital Implementation Guide*, the *Planning Guide* has been substantially restructured. Originally, the *Planning Guide* contained very granular detail about how to complete each planning activity suggested in the *Planning Guide*. With the advent of the *Hospital Implementation Guide*, we were able to move this detail to the *Hospital Implementation Guide* and make the *Planning Guide* a higher-level description of the complete planning process. We believe that this will allow far more audiences to benefit from the *Planning Guide* while preserving very important details for those who lead and facilitate the planning process.

The original version of the *Planning Guide* was organized into three overarching sections – pre-event preparedness, intra-event response, and post-event recovery. After completing the critical resource shortage response planning process at Norfolk General, we realized that, as part of the planning process, Norfolk General completed many of the tasks described in the intra-event and post-event sections of the *Planning Guide*. After much thought and deliberation, we decided to collapse the three sections into one section – pre-event preparedness. All of the activities in the *Planning Guide* are designed to be conducted pre-event and used to respond to a CRSE and position the Planning Unit for a quick recovery. We believe that condensing these three sections adds to the usability and broad appeal of the *Planning Guide*.

Finally, as discussed above, as part of the CDC grant project, we have developed an *Implementation Toolkit* as a companion to the *Planning Guide*. The *Planning Guide* has been written to apply to all HMDOs, from hospitals to EMS providers to long term providers and all providers in between. The *Hospital Implementation Guide*, by contrast, is specifically designed for acute-care hospital providers. It contains many of the lessons learned from the Norfolk General pilot project, which will apply primarily to and be most helpful for hospitals. The Georgia Core Team has asked Troutman Sanders to develop an implementation guide specific to EMS providers, which is expected to be completed in late 2009. In the future, we hope to be able to develop implementation guides specific to each type of HMDO that should engage in critical resource shortage response planning.



We hope that this *Planning Guide* will be a useful tool for HMDOs to use in their CRSE preparedness efforts. Any questions about the *Planning Guide* can be directed to Dr. Marissa Levine at (804) 864-7026 or marissa.levine@vdh.virginia.gov, Steve Gravely at (804) 697-1308 or steve.gravely@troutmansanders.com or Erin Whaley at (804) 697-1389 or erin.whaley@troutmansanders.com.



DEFINITIONS

Ad Hoc Protocols: Protocols, as defined herein, created in the midst of an emergency or disaster to address unplanned or unforeseen critical resource shortage events.

Allocation: A response to a CRSE in which remaining amounts of a critical resource are extended by distributing the resource according to established criteria such that not all patients receive the critical resource even though they would have under the traditional standard of care.

Critical resource: A resource that is necessary to provide care to sustain human life, prevent permanent injury/disability or stabilize a patient experiencing a medical emergency. Critical resources can include people, places and things.

Critical Resource Advisory Group or CRAG: A diverse, multi-disciplinary body, composed of representatives of the member(s) of the Planning Unit, which is responsible for conducting the critical resource shortage response planning activities assigned to the Planning Unit.

Critical resource shortage event or CRSE: A circumstance in which a critical resource is depleted, and all alternate methods of obtaining the critical resource have been exhausted, such that remaining resources will not allow HMDOs to treat patients in accordance with the traditional standard of care.

Critical Resource Shortage Response Plan or CRSRP: The resulting plan that encompasses all of the decisions, frameworks, policies, and Protocols developed with the assistance of the *Critical Resource Shortages Planning Guide* and governs how the member(s) of the Planning Unit will respond to a critical resource shortage event.

Disaster or Emergency: Any (i) natural disaster including, but not limited to, any hurricane, tornado, storm, flood, high water, wind-driven water, tidal wave, earthquake, drought, fire, communicable disease outbreak, or other natural catastrophe that threatens or causes damage to property, human suffering, hardship, or possible loss of life or (ii) manmade disaster including, but not limited to, acts of war or terrorism by conventional, nuclear, radiological, chemical or biological means; or any industrial, nuclear, or transportation accident, explosion, fire, power failure or resource shortages that threaten or cause damage to property, human suffering, hardship, or possible loss of life.

Goal: The ultimate purpose that the Critical Resource Shortage Response Plan and associated Protocols are designed to accomplish. Examples of Goals used in existing literature on allocation of scarce resources during a disaster include, but are not limited to, greatest good for the greatest number, greatest good for the greatest number with side constraints, saving the greatest number of lives, and protecting societal infrastructure.



Governmental Protocols: Protocols, as defined herein, issued by federal, state, local or tribal governments. Governmental Protocols may be mandatory or voluntary and can be in the form of guidance, standards, allocation algorithms, and prioritization schemes.

Health and Medical Delivery Organization or HMDO: Pre-hospital, hospital, post-hospital, outpatient, home care, retail, safety net, and any other community healthcare providers. The term HMDOs should be construed broadly to include all healthcare professionals and facilities that provide any level of inpatient and outpatient care as well as emergency medical services organizations.

Member(s) of the Planning Unit: Those HMDOs within the Planning Unit who are participating in the critical resource shortage response planning process and will use the resulting Critical Resource Shortage Response Plan to respond to a critical resource shortage event. If the Planning Unit is made up of a single HMDO, then that HMDO is the only "member of the Planning Unit." If the Planning Unit is made up of a group of HMDOs, then each HMDO is a "member of the Planning Unit."

Modification: A response to a CRSE in which remaining amounts of a critical resource are extended by changing the way care is delivered with or by a critical resource such that all patients still receive the critical resource but not in the way that they would have received it under a traditional standard of care.

Planning Unit: The level at which critical resource shortage response planning occurs. The Planning Unit can be made up of a single HMDO, a group of HMDOs, a community, a region, a state, or a nation depending on the relationship, characteristics and needs of the HMDOs within that Planning Unit. The Planning Unit may remain constant for all activities in the *Planning Guide* or it may vary based on the task.

Protocol Development Subcommittee or PDS: A subcommittee of a Critical Resource Advisory Group that is formed to develop a Protocol for a specific critical resource.

Protocols: Plans created to respond to a critical resource shortage event, as defined herein, pursuant to which delivery of care provided with the scarce critical resource is modified or the scarce critical resource is allocated to accomplish the Planning Unit's Goal.

GLOSSARY OF ACRONYMS

AHRQ Agency for Health Research and Quality

CDC Centers for Disease Control and Prevention

CRAG Critical Resource Advisory Group

CRSE Critical Resource Shortage Event

CRSRP Critical Resource Shortage Response Plan

CRVA Critical Resource Vulnerability Analysis

GAEMS Georgia Association of Emergency Medical Services

GA DPH Georgia Division of Public Health

HMDO Health and Medical Delivery Organization

ICS Incident Command Structure

PDS Protocol Development Subcommittee

VDH Virginia Department of Health

VHHA Virginia Hospital and Healthcare Association

PLANNING GUIDANCE

Chapter 1. Develop the critical resource shortage response planning infrastructure

Developing an ethically sound and implementable Critical Resource Shortage Response Plan (CRSRP), which includes Protocols for altering traditional standards of care, does not just happen—it requires significant planning. Advance planning allows Health and Medical Delivery Organizations (HMDOs) to anticipate many scenarios that may arise during an actual emergency or disaster and provide guidance to those making decisions during the event. Planning also allows for time to discuss and debate issues away from the chaos and intense pressures of an emergency event. Creating a planning infrastructure that fosters these discussions is an important preliminary step that will set the tone for the entire planning process. Outlined below is a suggested process for assembling the proper team to do this important work.

- 1.1. **Identify the "Convener."** Identifying a person or organization to serve as a "Convener" will enhance the likelihood of success. The Convener will not necessarily be required to lead the planning process, but the Convener should be able to actively engage key stakeholders.
- 1.2. Establish an "Implementation Team." The "Implementation Team" will be a small group of critical stakeholders who will be responsible for working closely with the Convener to guide, manage, oversee and facilitate the critical resource shortage response planning process. The Implementation Team will also be responsible for working with the Convener to determine the Planning Unit for key activities in the *Critical Resource Shortages Planning Guide* (*Planning Guide*) (see Section 1.4) and establishing a Critical Resource Advisory Group (CRAG) for each Planning Unit (see Section 1.5).
- 1.3. Identify a resource to facilitate the planning activities in the *Planning Guide*. Planning to address shortages of critical resources is a difficult and complicated task. While the *Planning Guide* presents a clear, systematic method for approaching this planning, it is not easy work. The Planning Unit's activities will benefit substantially from the use of a resource who can facilitate this process effectively. This resource will be responsible for working with the Implementation Team to prepare a schedule of planning activities, developing materials for meetings of the CRAGs, facilitating CRAG meetings to help participants reach consensus, capturing consensus points in summary documents, and designing and conducting exercises to test the CRSRP.
- 1.4. Determine the "Planning Unit" for key activities in the Planning Guide. It is important to assign each key activity in the Planning Guide to a Planning Unit that has responsibility for seeing that the activity is completed. The Planning Unit can be a single HMDO, a group of HMDOs, a community, a region, a state, or a nation depending on the relationship, characteristics and needs of the HMDOs within the Planning Unit. The Planning Unit may remain constant for all activities in the Planning Guide or it may vary based on the activities. As you review the remainder of this Planning Guide, determine the most appropriate Planning Unit for each activity.

- 1.5. Establish Critical Resource Advisory Groups for each Planning Unit identified in Section 1.4. For each Planning Unit identified in Section 1.4, the Implementation Team will need to establish a diverse, multi-disciplinary body, composed of representatives of the member(s) of the Planning Unit. This body the Critical Resource Advisory Group or CRAG will be responsible for conducting the critical resource shortage response planning activities assigned to the Planning Unit (see Section 1.4). While the exact composition of each CRAG will depend on the Planning Unit that it represents, each CRAG should have a strong combination of stakeholders. If the Implementation Team chooses to have multiple Planning Units be responsible for various key activities, it will have to establish multiple CRAGs and be responsible for management, oversight and coordination of these groups.
- 1.6. Set forth clear expectations for the critical resource shortage response planning process. The Implementation Team, together with members of each CRAG, must agree upon the expectations of participation in the group related to completion of the CRAG's assigned activity(ies) and sources of funding to support these activity(ies). Reaching an understanding on these issues at the beginning of the process will help the CRAG operate effectively and increase the likelihood that the CRAG will be successful in its tasks.

Chapter 2. Conduct a Critical Resource Vulnerability Analysis

HMDOs require and use numerous critical resources in the care that they provide. Many of these resources are taken for granted because in today's healthcare system, they are readily available for all patients in need. Supply chain management has become so effective that it is difficult for HMDOs to imagine a situation in which critical resources are truly scarce. This makes it very difficult for them to identify critical resources, much less prioritize them for planning purposes. The Critical Resource Vulnerability Analysis (CRVA) is a systematic approach to prioritizing these resources and ultimately identifying those resources that are the highest priority for Protocol development (see Chapter 5).

- **2.1. Develop a list of critical resources.** The CRAG should develop a comprehensive list of all critical resources used by the member(s) of the Planning Unit (e.g., those resources necessary to sustain human life, prevent permanent injury/disability, or stabilize a patient experiencing a medical emergency).
- **2.2. Prioritize the list of critical resources.** The CRAG will likely develop a long list of critical resources, all of which cannot be addressed at once through the development of a resource-specific Protocol. As a result, prioritization of the identified critical resources is crucial to allow Protocol development efforts to focus on the critical resources that are most at risk of being depleted during an emergency or disaster. Those resources which are likely to be depleted quickly and have a significant impact on the way that care is provided should be given high priority.
- 2.3. Identify mechanisms for mitigating depletion of the resources identified in Section 2.1 and prioritized in Section 2.2. The CRSRP and associated Protocols are intended to be used as a last resort after the member(s) of the Planning Unit has implemented and exhausted its surge plans and other plans to mitigate resource shortages. While

finalizing the prioritization of the critical resources identified in Section 2.1, the CRAG should identify existing mechanisms for mitigating depletion of each resource. After these mechanisms have been identified, the CRAG should evaluate them to determine if they are sufficient to address a disaster resulting in high demand for each resource.

- 2.4. Determine which critical resources should be immediately considered for Protocol development. Even after following the process outlined in the first three sections of this Chapter 2, the CRAG may have a list of more resources than it can realistically develop Protocols to address. To select the top resources for Protocol development, the CRAG should examine both the prioritization and the availability of mechanisms to mitigate shortages. If these mechanisms appear to be sufficient to allow the member(s) of the Planning Unit to surge its supply of a resource and accommodate a prolonged increase in demand, these resources may not be a priority for Protocol development. Through this analysis, the CRAG should identify the most important resources for which Protocols should be developed and forward its conclusions to the CRAG for the Planning Unit that will be responsible for Protocol development.
- 2.5. Revisit the Critical Resource Vulnerability Analysis at appropriate intervals or immediately following an emergency or disaster. Over time, the emergencies and disasters that threaten a Planning Unit, the resources that are considered "critical" and even the patient population of a Planning Unit may change. As a result, the Critical Resource Vulnerability Analysis should be re-visited at appropriate intervals or after an emergency or disaster. Relevant, up-to-date plans will enable the Planning Unit to best respond in the face of a critical resource shortage event (CRSE).

Chapter 3. Develop an ethical framework that will guide the development of the Critical Resource Shortage Response Plan and associated Protocols

There is a relative consensus across the country that HMDOs will use their best efforts to appropriately modify the way that care is provided and allocate scarce resources during a critical resource shortage event. There is much less consensus, if any, on exactly what "appropriately" means and how HMDOs will make this decision. Your Planning Unit needs a guiding ethical framework if it hopes to make these very complicated decisions in a way that will be recognized by all as having a solid ethical foundation. This section of the *Planning Guide* walks through a three step process to develop this ethical framework. The three step process encourages the CRAG for the Planning Unit responsible for this activity to (i) identify ethical principles, (ii) define the Goal(s) of Protocols, and (iii) determine conceptually how to alter standards of care and allocate scarce resources to meet its Goal(s). The ethical framework created in this Chapter will become part of the Planning Unit's Critical Resource Shortage Response Plan and will inform the development of all other sections of the CRSRP, including resource-specific Protocols.

3.1. Develop a set of ethical principles that will form the foundation of the Planning Unit's ethical framework. Almost every ethical framework is built upon a set of core principles. The CRAG's first step in developing an ethical framework is to identify the principles that will form the basis of the framework. Current literature on ethics and

allocation of scarce resources suggests numerous principles that the CRAG may adopt. In some states, a statewide or regional task force may have already identified these ethical principles. In states where these principles have not yet been determined, the CRAG must decide which of the ethical principles to incorporate into its framework based on the needs, characteristics, and values of the member(s) of the Planning Unit.

- 3.2. **Define the Goal(s) of CRSRP and Protocols.** Once the CRAG has developed ethical principles for the framework, it will need to apply these principles to define the Goal of the CRSRP and associated Protocols. The Goal is the ultimate purpose that the CRSRP and Protocols are designed to accomplish. Examples of Goals used in existing literature on allocation of scarce resources during a disaster include, but are not limited to, preserving societal infrastructure, preventing morbidity and mortality, and doing greatest good for the greatest number. To the extent that a relevant governmental entity has not already established the Goal, the CRAG will need to do so.
- 3.3. Determine conceptually how the ethical principles and the Goal(s) will impact allocation of scarce resources during a CRSE. The ethical principles and Goal(s) will inform the development of the Protocols used to govern the response to a CRSE. Almost every Protocol Development Subcommittee will confront some similar ethical questions regarding allocation of scarce resources. If a relevant government entity has not already done so, the CRAG should use the ethical principles and Goal(s) to provide guidance on three common allocation issues: withdrawal and reallocation decisions; withholding decisions; and "exclusion" criteria. These three areas are referred to as "implementation specifications."

Chapter 4. Develop an operational infrastructure that will support an effective response to a critical resource shortage event

An effective response to a CRSE will require that each Planning Unit and each member(s) of a Planning Unit have an infrastructure that supports and aids the implementation of a CRSRP. While the majority of HMDOs have an emergency response infrastructure, many have not yet developed the type of infrastructure that will be needed to efficiently implement a CRSRP and the associated Protocols. Development of this infrastructure prior to an event is critically important so that all Protocols, regardless of whether these Protocols are mandated by a governmental entity or developed by a single HMDO for its own use, can be implemented at the point of care in a consistent manner. Without this consistent operational infrastructure, the member(s) of the Planning Unit will not be able to successfully use Protocols, which may render them moot. To avoid this result, the Planning Unit and each of its members is encouraged in this chapter to develop the basic framework of an operational infrastructure that will support the consistent development, implementation and operationalization of the CRSRP and associated Protocols. Recognizing that each Protocol may present separate implementation and operationalization challenges, the Planning Unit is encouraged to further define the details of this basic framework as each Protocol is developed (see Chapter 5).

4.1. Determine how the Planning Unit will activate and terminate its CRSRP. As with all plans, someone within the Planning Unit will have to authorize the activation of the CRSRP once a critical resource shortage event occurs and terminate the CRSRP once the event ends. For those Planning Units with a unified incident command structure, these

- decisions will probably be made by the Incident Commander. For those Planning Units without an incident command structure, someone will have to be granted the authority to make these decisions. Regardless, it is likely that the person charged with making these decisions will not be familiar with the concept of, or the decisions presented by, a CRSE. As a result, it is critical that the CRAG develop mechanisms and a process to identify the beginning and the end of a critical resource shortage event so that the decisions to activate and terminate the CRSRP can be made in a timely and appropriate manner.
- 4.2. Determine how the Planning Unit will activate and terminate each Protocol. The CRSRP will contain various Protocols for specific resources (see Chapter 5). The CRAG will need to determine whether activation of the CRSRP activates all Protocols contained therein or whether the Protocols will be activated separately based on specific resource levels. Likewise, the CRAG will need to determine whether each of the Protocols will be terminated once specific resources are restored or whether all Protocols will be terminated simultaneously with the termination of the CRSRP. If Protocols will be activated and terminated individually, the CRAG will need to develop mechanisms for making these important decisions.
- 4.3. Determine how resource allocation decisions will be made for individual patients using a Protocol. Once the CRSRP and associated Protocols are activated, individuals will have to apply the Protocols to make specific resource allocation decisions for individual patients. The CRAG will need to identify who at the point of care will be designated to make these decisions and, if multiple people are involved, how they will interact (e.g., coordination between triage officers and a triage committee). Because these decisions may have dire results for some patients, it is critically important to ensure that whatever processes the CRAG establishes result in the ethical and consistent application of the Protocol.
- 4.4. Develop the infrastructure that will support reviewing and revising the CRSRP and associated Protocols during an event. No matter how good a CRSRP and associated Protocols are, they cannot anticipate every circumstance that may arise during an event. Like all plans, the CRSRP and Protocols will need to be continually re-evaluated during a CRSE in light of the actual circumstances presented by the event and then revised accordingly. With respect to Protocols in particular, new clinical data may become available during the event which will make revisions to the Protocol imperative. The CRAG will need to develop an infrastructure for this review and revision process because without such an infrastructure, it is likely that this important step will be overlooked during the chaos of an event.
- 4.5. Develop a standard definition of "essential documentation." Obtaining appropriate documentation often poses a problem for HMDOs in the best of circumstances. During a CRSE, it is going to be even more difficult for HMDOs to complete documentation according to "normal" standards. The CRAG should determine what type of documentation is "essential" during a CRSE for the care and safety of the patient, the proper operation of Protocols, quality assessment, and reimbursement.
- 4.6. Establish expectations for compliance with the CRSRP and mechanisms for addressing non-compliance. Those who will be asked to operate under the CRSRP need to clearly understand what will be expected of them during a critical resource

- shortage event and what their role will be with respect to the Plan. It will be crucial that everyone understand that they must comply with the CRSRP, especially the Protocols, for the Plan to function as intended. If one fails to comply with the CRSRP and associated Protocols, it will have a detrimental impact on the response and operations of the member(s) of the Planning Unit. The CRAG should develop mechanisms to address non-compliance through appropriate disciplinary mechanisms so that the member(s) of the Planning Unit are prepared to handle these situations.
- 4.7. Identify what resources will be available to provide psychological and emotional support to providers of care, patients and their families during a CRSE. A CRSE will be a very trying time for everyone, especially providers of care, their employees, patients and their families. All of these groups will likely need much more psychological and emotional support than normal. The CRAG should identify psychological and emotional support resources that will be available during and after a CRSE to provide needed support.
- 4.8. Develop a general "palliative care" strategy for addressing the needs of patients who do not receive critical resources. During a CRSE, there will be patients who present for care who will not receive the level of care or the resources that they would under a traditional standard of care because the resources required for such care are not available. These patients cannot be abandoned. The member(s) of the Planning Unit should provide some level of care to these patients, including "palliative care." Since "palliative care" presents many challenges in "normal" times, the CRAG should develop a strategy for addressing "palliative care" during a CRSE so that it can be provided effectively.
 - 4.8.1. **Determine the goal of "palliative care" during a CRSE**. Palliative care is traditionally associated with end-of-life care. During a CRSE, however, palliative care may be used primarily for other purposes such as symptom control and comfort care. For this reason, it is important for the CRAG to determine its goal for "palliative care" during a CRSE.
 - 4.8.2. Develop a standard definition of "palliative care" during a CRSE based on the goal of such care as identified in Section 4.8.1. Once the CRAG has determined the goal of "palliative care" during a CRSE, the CRAG should capture this goal in a standard definition. Use of a standard definition will allow the Planning Unit to easily and quickly communicate to multiple audiences what "palliative care" during a CRSE means to the member(s) of the Planning Unit.
 - 4.8.3. Identify mechanisms for providing "palliative care" during a CRSE. "Palliative care" presents many challenges in "normal" times and can be difficult for HMDOs to provide. During a CRSE when more patients than normal may need "palliative care," it will be even more challenging to provide. The CRAG will need to identify mechanisms for providing this greater amount of "palliative care" during a CRSE.
- 4.9. Develop a comprehensive communication plan related to the operational infrastructure that will support the use of the CRSRP during a CRSE. Information about the activation of, content of, modifications to, and termination of the CRSRP and associated Protocols will have to be communicated to various audiences both before and

during an event. As part of the comprehensive communication plan, the CRAG should memorialize decisions made about the operational infrastructure and communicate these decisions to other CRAGs involved in the critical resource shortage response planning process.

Chapter 5. Identify or develop resource-specific Protocols

Protocols are algorithms which describe how the Planning Unit will alter the "standard of care" for a specific critical resource to respond to a shortage of that resource during a disaster. Protocols include both a description of how care provided by or with the critical resource will be modified to "stretch" the resource and how the resource will be allocated after modifications have been made but demand still exceeds supply.

If no mandatory federal, state or local Protocols exist for the critical resource in question, the Planning Unit, through its CRAG, will have to develop its own Protocol for the resource. The CRAG is encouraged to develop Protocols for critical resources according to the prioritization established in the Critical Resource Vulnerability Analysis (see Chapter 2). Protocols should be based on an ethical framework (see Chapter 3) and should build upon a consistent operational infrastructure (see Chapter 4).

- 5.1. Establish a subcommittee of the CRAG to develop the content of and the plan to implement a Protocol for a specific critical resource. The Planning Unit will likely want to develop multiple Protocols to address multiple resources if a governmental entity has not already done so. Because it would be too onerous for the entire CRAG to develop all Protocols, the CRAG should establish subcommittees, each of which will be tasked with developing a Protocol for a specific critical resource (Protocol Development Subcommittees or PDS). Regardless of the source of the Protocol the Protocol Development Subcommittee or a governmental entity the Subcommittee will need to develop the operational plan for implementation of the Protocol.
- 5.2. Identify the existing surge plan for the critical resource and if one does not exist, create it. Many HMDOs already have surge plans in place to address basic resource shortages during a disaster. These surge plans provide mechanisms for increasing an HMDO's capacity to provide care by augmenting existing resources. Many HMDOs, however, have not established a "post-surge" plan to address a CRSE. The Protocols that will be developed through the use of the *Planning Guide* are designed to address this post-surge gap. Because the altered standards of care described in the Protocols are a severe response, the Protocols should only be used post-surge. This means that it is important that the member(s) of the Planning Unit ensures it has adequate surge plans in place for each critical resource so that it can delay the need to implement a Protocol.
- 5.3. Identify any Governmental Protocols related to the specific critical resource. Governmental Protocols Protocols issued by federal, state, local or tribal governments come in a variety of forms such as guidance, standards, allocation algorithms, and prioritization schemes. Some of the Governmental Protocols may be mandatory while others may remain voluntary. Before developing its own Protocol for a critical resource, the PDS should identify whether there are any existing Governmental Protocols that address the resource. If such Governmental Protocols do exist, the PDS

- should determine whether they are mandatory or voluntary. If they are mandatory, each member of the Planning Unit should create an infrastructure to implement the Governmental Protocol at the point of care (see Section 5.5). If they are voluntary or if Governmental Protocols do not exist, the PDS should continue developing a Protocol that the member(s) of the Planning Unit can use to address a critical shortage of the specific resource in question.
- **5.4. Develop a Protocol for a specific critical resource.** Protocols are algorithms which describe how the member(s) of the Planning Unit will alter the standard of care for a specific critical resource to respond to a shortage of that resource during a disaster. Protocols should include two basic components: (1) a description of how care provided by or with the critical resource will be modified to "stretch" the resource; and (2) a description of how the resource will be allocated after modifications have been made but demand still exceeds supply. The PDS identified in Section 5.1 will develop a Protocol to address the shortage of the specific critical resource in question. The Protocol should be grounded in the ethical framework established in Chapter 3 and the operational infrastructure created in Chapter 4.
 - 5.4.1. Determine how care provided by or with the critical resource will be modified during a CRSE. If an HMDO is unable to meet the demand for a resource even after instituting its surge plan, the HMDO will have to modify how care is provided by or with the critical resource. Modifications are necessary to (i) "stretch" the resource as much as possible to allow the HMDO to provide as much care as possible in a way that meets its ethical Goal, and (ii) delay the need to allocate the resource. The PDS will be responsible for looking at how care is provided by or with the critical resource in "normal" times and determining how that care can be modified during a CRSE.
 - 5.4.2. Determine how the critical resource will be allocated during a CRSE. If an HMDO has implemented its surge plan and modified the way care is provided by or with the critical resource as much as possible, and demand for the resource still exceeds supply, the HMDO is going to have to allocate the resource. This type of allocation results in some patients receiving the critical resource and some patients not receiving the resource. Because allocation decisions are very difficult decisions for both HMDOs and patients, they must be made in an ethically sound manner. The PDS will be responsible for developing a mechanism (e.g., standard, algorithm) that supports ethical allocation decisions.
- 5.5. Determine how the Protocol will be implemented. Once the PDS has developed the Protocol, it will need to determine how the Protocol will be implemented during a CRSE. The implementation of the Protocol can be just as difficult and complex as developing the Protocol. As a result, the PDS is encouraged to "drill down" on the basic implementation infrastructure created in Chapter 4 to create an operational plan, which describes exactly how the Protocol will be implemented and operationalized.
 - 5.5.1. Decide who will be the "triage officer(s)" and/or "triage committee members" for the Protocol, if applicable. In Section 4.3, the CRAG identified a basic implementation infrastructure likely consisting of a triage officer(s) and/or triage committee(s). If the CRAG decided that there will be officer(s) and/or

- committee(s) for each critical resource, identify which types of individuals should serve as the triage officer(s) and/or triage committee(s) for the Protocol.
- 5.5.2. Identify any additional information that will be needed during an event to finalize, revise, modify or enhance the Protocol. It is likely that in developing the Protocol, the PDS will identify certain types of information that are needed to validate or refine the Protocol. Much of this information will not be available until the event occurs. The PDS should create a list of the information needed during an event to finalize, revise, modify, or enhance the Protocol and a mechanism for obtaining and analyzing this information.
- 5.5.3. **Develop a mechanism for revising the Protocol during a CRSE.** No matter how good a Protocol is, it will have to be refined during a CRSE based on new information as it becomes available. The PDS should develop a mechanism for making these revisions during a CRSE.
- 5.5.4. **Determine when the Protocol will be activated, if applicable.** In Section 4.2, the CRAG determined whether activation of the CRSRP will activate all Protocols or whether each Protocol will be activated separately based on specific resource levels. If the CRAG concluded that each Protocol will be activated separately, the PDS should establish a process for activating the Protocol which includes the identification of triggering events. This process should reflect that activating the Protocol is likely a drastic change in the way that care is provided and is a serious decision that cannot be made hastily.
- 5.5.5. Determine when and how the Planning Unit will move between tiers of the Protocol, if applicable. If the Protocol has multiple tiers, the PDS should determine when and how the Planning Unit will move between tiers. Like activation of the Protocol itself, the decision to move between tiers should not be taken lightly because moving to a "higher" tier will further alter the standard of care and eventually result in allocation. The PDS should establish mechanisms for moving between tiers of the Protocol.
- 5.5.6. Determine when the Protocol will be terminated and the Planning Unit will return to a "normal" standard of care, if applicable. In Section 4.2, the CRAG determined whether the Planning Unit will terminate all Protocols simultaneously or whether each Protocol will be terminated separately based on specific resource levels. If the CRAG concluded that each Protocol will be terminated separately, the PDS should establish a process for terminating the Protocol which includes the identification of triggering events. This process should reflect that terminating the Protocol will likely be a difficult decision to make. There will be a delicate balance between terminating the Protocol too early, which may lead to a re-activation of the Protocol, and too late, which will lead to the use of "altered" standards of care past the time that they were necessary to address the CRSE.
- 5.6. Establish parameters around the type of documentation needed to support the Protocol and the type of documentation that the member(s) of the Planning Unit will be expected to complete related to the Protocol. As in normal times, documentation will be essential during a CRSE. What "essential documentation" is,

however, will likely change during the event. Based on the definition of "essential documentation" created in Section 4.5, the PDS should identify the specific type of information that is essential for the care and safety of the patients to whom the Protocol is applied, the proper operation of the Protocol, quality assessment of the Protocol, and reimbursement for care provided pursuant to the Protocol.

- 5.7. Coordinate the content and implementation of the Protocol with other Protocols being developed by other Protocol Development Subcommittees. While the Protocol is resource specific, the resource does not exist in isolation. It likely interacts with numerous other resources to provide comprehensive care. As the PDS is conducting its activities, it should coordinate with other Subcommittees working on Protocols that may interact with its specific Protocol. This coordination is important to ensuring a comprehensive and cohesive response to critical resource shortage events.
- **5.8. Memorialize the Protocol in writing.** The PDS should reduce its Protocol to writing and submit it to the CRAG overseeing the work of the Protocol Development Subcommittees. The CRAG can then submit the Protocols for approval and integration (see Chapter 9). In written format, the Protocols can be more readily shared with others and implemented during an event.
- 5.9. Conduct training related to the content and implementation of the Protocol. Once the Protocol is finalized and approved, the member(s) of the Planning Unit will need to conduct significant training on its content and implementation. The PDS should identify the categories of individuals who need to be trained and the type of training that they should undergo and, together with trainers, develop content for these sessions.

Chapter 6. Create an infrastructure to support the development, implementation and operationalization of Ad Hoc Protocols during a critical resource shortage event

Given the vast number of critical resources used in healthcare today, the Planning Unit will not be able to develop Protocols to address the scarcity of all the resources identified in and prioritized by the Critical Resource Vulnerability Analysis (see Chapter 2). Moreover, the Planning Unit cannot anticipate all of the potential critical resources that may become scarce during a disaster or emergency. These unplanned or unforeseen CRSEs will cause the Planning Unit to have to develop Protocols to address the scarcity in the midst of an event. These Protocols developed in the midst of an event are called "Ad Hoc Protocols." The Planning Unit should prepare for this situation by creating an infrastructure that will support the development, implementation and operationalization of Ad Hoc Protocols during a CRSE.

6.1. Determine how the Planning Unit will decide that, in the midst of a disaster, development of an Ad Hoc Protocol is required. To help ensure an effective response to a disaster and any resulting CRSEs, it is important for the CRAG to determine who will decide that development of an Ad Hoc Protocol is required. The person(s) charged with the responsibility for identifying the need for an Ad Hoc Protocol and activating the process for developing this Protocol will also likely be in charge of many other aspects of the disaster response. It is also highly likely that this person(s) will not have experience with identifying a CRSE. To help this person(s) discharge his duties

- effectively, the CRAG should determine the types of information that will suggest that a CRSE exists or is about to exist and that development of an Ad Hoc Protocol is necessary to respond to the CRSE.
- 6.2. Develop the process by which an Ad Hoc Protocol will be created in the midst of a disaster. Development of a Protocol takes a significant amount of time and resources. Prior to an event, it is appropriate to dedicate resources to Protocol development. During an event, however, time and resources will be scarce, but Ad Hoc Protocols will still need to be developed. To help facilitate efficient development of Ad Hoc Protocols during an event, the CRAG should create an Ad Hoc Protocol development process. The process will likely be similar to the one used by the Protocol Development Subcommittees prior to the event (see Chapter 5) but reduced to its essential elements.
- 6.3. Develop a standard mechanism for communicating the creation, implementation and operationalization of Ad Hoc Protocols. During the event, it will be important to communicate the creation, implementation and operationalization of Ad Hoc Protocols with various audiences. While the precise messages surrounding a specific Ad Hoc Protocol cannot be developed until the CRSE occurs and the Ad Hoc Protocol is developed, a general structure and communication plan surrounding Ad Hoc Protocols should be developed as part of the Planning Unit's preparedness activities and comprehensive communication plan (see Chapter 10).

Chapter 7. Engage in collaborative planning and coordination with other Health and Medical Delivery Organizations

The complete healthcare delivery model will vary from community to community but usually includes a complex combination of pre-hospital, hospital, post-hospital, outpatient, home care, retail, safety net, and other community providers (collectively, "Health and Medical Delivery Organizations" or "HMDOs"). Any disaster or other emergency that is disruptive enough to create a CRSE for one HMDO is also going to significantly impact other HMDOs. While each event is unique, the ability of all HMDOs to render care is likely to be affected.

During "normal" times, all HMDOs have varying degrees of interaction. Based on the type of HMDO, these interactions may be more or less extensive and may be the result of varying degrees of planned clinical and managerial integration. During a disaster which places stress on the healthcare system, each HMDO may need to rely more heavily on other types of HMDOs to care for patients.

The member(s) of the Planning Unit must recognize its interdependencies during a disaster and collaboratively plan with other HMDOs to ensure a coordinated response to CRSEs. This chapter addresses the planning considerations the Planning Unit should consider in conjunction with other HMDOs.

7.1. Identify with which HMDOs the Planning Unit will engage in coordinated critical resource shortage response planning. There are various types of providers that are included under the title of HMDOs. Recognize that collaboration with each type of HMDO may be slightly different based on the HMDO's role in the healthcare system. Given the sheer number of HMDOs, however, it will be difficult for the CRAG to

- establish a collaborative planning relationship with all HMDOs. Instead, the CRAG should engage those types of HMDOs that will have the most significant impact on the ability of the member(s) of the Planning Unit to effectively implement the CRSRP.
- 7.2. Create a communication strategy with other HMDOs about the Planning Unit's CRSRP and associated Protocols. There will likely be numerous HMDOs identified in Section 7.1. It is probably not realistic to expect the CRAG to communicate with each HMDO individually. Instead, it may be more appropriate and efficient for the CRAG to communicate with a central point of contact or some representative body of each type of HMDO. Regardless, the CRAG needs to create a strategy for communicating with all HMDOs before, during and after a CRSE.
- 7.3. Understand how other HMDOs' responses to a CRSE may impact the member(s) of the Planning Unit. It is important for the member(s) of the Planning Unit to understand that all other HMDOs may face shortages of critical resources during a disaster. This could involve personnel, supplies, equipment, or critical support commodities. Shortages in some or all of these critical resources will require that these other HMDOs alter their operations during a disaster. If these other HMDOs do alter their operations, like the member(s) of the Planning Unit, they will likely do so in response to governmental emergency orders or to support their own continuity of operations. The member(s) of the Planning Unit needs to understand how these other HMDOs' responses to a CRSE may impact it so that it can plan and respond accordingly.
- 7.4. Engage in discussions with other HMDOs about how they might change their scope of services during a disaster based on the Planning Unit's CRSRP and associated Protocols. To use the CRSRP and associated Protocols most effectively, the member(s) of the Planning Unit may ask other types of HMDOs to change their scope of services during a CRSE. This change can be either an expansion or a reduction in the services they normally provide.
 - 7.4.1. Determine whether other HMDOs will expand their scope of services. In a CRSE, it is possible that a component of your Planning Unit's CRSRP or associated Protocols will be to ask other HMDOs to expand the scope of services they provide in an effort to decompress the member(s) of the Planning Unit. In some cases, this will mean that some HMDOs are asked to provide services that they do not normally provide and that they may even be prohibited from providing under state law or regulation. Obviously, these regulatory issues must be addressed by the other HMDOs, the member(s) of the Planning Unit and the relevant governmental agencies.
 - 7.4.2. Determine whether other HMDOs will reduce their scope of services. In a CRSE, it is possible that one component of your Planning Unit's CRSRP or associated Protocols will be to ask other HMDOs to reduce the scope of services they provide in an effort to allow the member(s) of the Planning Unit to most effectively and efficiently apply the CRSRP and associated Protocols. The CRAG should engage other HMDOs in these discussions now to avoid conflict and confusion during an event.

- 7.5. Determine whether the member(s) of the Planning Unit will participate in any cooperative initiatives with other HMDOs. In addition to collaborating with other HMDOs, the member(s) of the Planning Unit may actually want to enter into cooperative initiatives with these other HMDOs to support a response to a CRSE. These initiatives can take many forms including, but not limited to, cooperative stockpiling agreements, ambulance re-stocking agreements or transfer agreements. The CRAG should explore such initiatives to determine whether they are feasible and desirable.
- 7.6. Establish parameters around the type of documentation needed to support the relationship between the member(s) of the Planning Unit and other HMDOs. As in "normal" times, documentation will be essential during a CRSE. What "essential documentation" is, however, will likely change during the event. Based on the definition of "essential documentation" created in Section 4.5, the CRAG should work with other HMDOs to collectively determine how "essential documentation" will be collected and shared during a CRSE.

Chapter 8. Determine how the Critical Resource Shortage Response Plan will be evaluated and maintained

Once the basic components of a CRSRP are developed, the CRAG will need to determine how to evaluate and maintain the Plan over time. The evaluation and maintenance elements of the CRSRP are no less crucial than the operational and ethical frameworks and the Protocols themselves. Without proper evaluation and maintenance what appears to be a good plan on paper may not work in the midst of an event.

- 8.1. Conduct activities to evaluate the CRSRP. Once the full content of the CRSRP is created, it must be evaluated to determine whether it can be implemented to accomplish its intended purposes. This evaluation can take many different forms including a simulation, a table top exercise or a drill. Whatever form it takes, the evaluation should be designed to determine whether the CRSRP will work in the event of a critical resource shortage event. Like all other emergency and disaster response plans, evaluations of the CRSRP should be conducted on a routine basis.
- **8.2. Revise the CRSRP as necessary.** The CRSRP should be revised based on the results of, and lessons learned from, the evaluation activities conducted pursuant to Section 8.1, changed circumstances in the Planning Unit, or after an actual critical resource shortage event. These revisions are a critical step in developing and maintaining a successful CRSRP.
- 8.3. Create a mechanism for periodically reviewing and updating the CRSRP. In addition to revising the CRSRP after an evaluation or an actual critical resource shortage event, the CRSRP should be reviewed at set intervals to make sure that it still reflects the most current thinking on critical resource shortage preparedness and response. This review could coincide with other scheduled reviews of the Planning Unit's emergency preparedness and response plans. Based on the results of the review, the CRSRP may need to be updated.

Chapter 9. Obtain approval of the Critical Resource Shortage Response Plan and integrate it into all relevant emergency operations plans

Once all of the elements of the Critical Resource Shortage Response Plan have been compiled or developed, the Plan will have to be approved by the relevant stakeholders and integrated into the appropriate emergency operations plans. Without this approval and integration, the Plan will have little chance of being used effectively during an event.

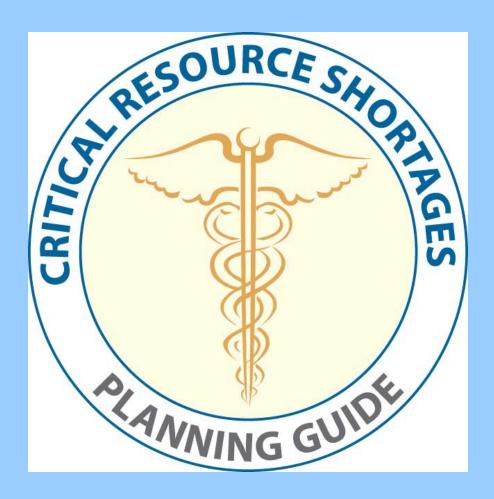
- 9.1. Obtain approval for the CRSRP from the relevant stakeholders. Obtaining approval of the CRSRP from all relevant stakeholders is a crucial step to ensuring the effectiveness of the Plan. By seeking and obtaining approval, the Planning Unit is building buy-in to the CRSRP, which will hopefully enhance compliance with the Plan during an event. The type of approval required and the process for obtaining it will vary according to the number and types of members of the Planning Unit. CRSRPs that are developed by a Planning Unit with multiple members may need to be approved by both the Planning Unit and each individual member of the Planning Unit. This multi-level approval can take a significant amount of time and effort, but it is a necessary step in the process.
- 9.2. Integrate the CRSRP into all applicable emergency operations plans. Once the CRSRP has been approved, the Planning Unit and each of its members should review its respective emergency operations plans and revise them to incorporate and integrate each element of the CRSRP: the Critical Resource Vulnerability Analysis, the ethical framework, the operational infrastructure, resource-specific Protocols, the process for developing Ad Hoc Protocols, and the mechanism for evaluating and maintaining the Plan. This integration is critical for a coordinated, effective response to a critical resource shortage event.

Chapter 10. Develop comprehensive communication plans with strategies addressing communications to key audiences

To many, the concept of modifying or allocating care in response to a critical resource shortage event is something that they have not thought much about. Those who have thought about it are usually troubled by the types of life and death decisions that HMDOs will be forced to make. Part of the Planning Unit's CRSE preparedness, response and recovery activities must include communication with various audiences about CRSEs in general and the Planning Unit's CRSRP in particular. The main audiences for these types of communication will be the "6 Ps" – providers, patients, partners, the public, the press, and politicians. Each message must be carefully tailored for the intended audience to accomplish a defined objective and have the greatest impact. This chapter provides a framework for Planning Units to use when developing these communication plans.

10.1. Develop a communication strategy tailored to providers. The Planning Unit will need to communicate with HMDOs and their staffs as part of the Planning Unit's planning, response and recovery activities. This communication is essential to ensure that those at the point of care understand the consequences of a CRSE, the Planning Unit's response plan and what is expected of them as providers of care.

- 10.2. Develop a communication strategy tailored to patients. The Planning Unit will need to communicate with patients as part of the Planning Unit's planning, response and recovery activities. This communication is essential to ensure that those who are receiving or will receive care during a CRSE understand the consequences of a CRSE and the impact the Planning Unit's CRSRP will have on the way HMDOs provide care.
- 10.3. Develop a communication strategy tailored to partners of the member(s) of the Planning Unit. The Planning Unit will need to communicate with the partners of the member(s) of the Planning Unit including, but not limited to, vendors, volunteers and other organizations or individuals who are integral to the operations of the member(s) of the Planning Unit. This communication is essential to ensure that those partners that support the member(s) of the Planning Unit are aware of the threat of, planned response to, eventual existence of, and impact of critical resource shortage events. Such knowledge will help these partners to better support the Planning Unit's CRSRP.
- 10.4. Develop a communication strategy tailored to the public. The Planning Unit will need to communicate with the public as part of the Planning Unit's planning, response and recovery activities. This communication is essential to ensure that the general public understands the consequences of a CRSE and the type of responses that will be required.
- 10.5. Develop a communication strategy tailored to the press. The Planning Unit will need to communicate with the press as part of the Planning Unit's planning, response and recovery activities. During a CRSE, the press will cover the disaster that created the CRSE on a "24/7" news-cycle. Recent disasters have demonstrated how press coverage can help or hurt an effective disaster response. To assist in making press coverage of the CRSE and the Planning Unit's response as beneficial as possible, the Planning Unit should begin educating the press now on its CRSE preparedness efforts and keep it informed of developments during its response and recovery.
- 10.6. Develop a communication strategy tailored to politicians. The Planning Unit will need to communicate with various politicians as part of the Planning Unit's planning, response and recovery activities. During a CRSE, certain politicians will likely become a key audience since they may be heavily involved in emergency management or communications with their concerned constituents. This communication from the Planning Unit to the politicians is essential to ensure that the politicians are armed with good information on which they can base their own messaging.



We hope that you found this *Planning Guide* useful and informative. Any questions about the *Planning Guide* or *Implementation Toolkit* can be directed to Dr. Marissa Levine at (804) 864-7026 or marissa.levine@vdh.virginia.gov, Steve Gravely at (804) 697-1308 or steve.gravely@troutmansanders.com or Erin Whaley at (804) 697-1389 or erin.whaley@troutmansanders.com.